REMARKS

Amendments to the Claims

Claims 1-3, 5-9, 11 are pending. Claims 4, 10, 12-23 are cancelled. Claim 1 is currently amended in the present response. The other claims are identical to the claims previously presented with our response dated November 20, 2008.

No new matter has been added.

Rejection of claims 1-3, 5-9 and 11 under 35 USC 112

Claims 1-3, 5-9 and 11 were rejected under 35 USC 112 for the following reasons.

The Examiner expressed the opinion that it was not clear as to whether a device or a person performs the process limitations "determining the presence or severity of ischemia in the tissue"; "directly measuring intracompartmental pH in the tissue"; and "using the intracompartmental pH measurement to diagnose the pathological condition".

The Examiner also expressed the opinion that it is not clear how "determining the presence or severity of ischemia in the tissue" can be performed "by inserting a pH sensor into the tissue".

Claim 1 has been re-written to clarify these matters. In particular, claim 1 has now been divided up more clearly into its constituent parts.

"Determining the presence or severity of ischemia in the tissue" has been moved into the introductory portion of the claim, and by adding the words "by the steps of", it is now clear that all of the following steps are leading to the determination of the presence or severity of ischemia.

Hence, it not the case that the presence or severity of ischemia is determined only by inserting a pH sensor into the tissue, but actually by all of the following steps.

It has also been clarified that the step of "directly measuring intracompartmental pH in the tissue" is performed by the pH sensor (a device).

It has also been clarified that the step of "using the intracompartmental pH measurement to diagnose the pathological condition" is performed by a person (who may or may not be using additional equipment to aid in the determination of ischemia and the diagnosis).

Hence, these objections are now moot.

Rejection of claims 1-3, 5-9 and 11 under 35 USC 101

Claims 1-3, 5-9 and 11 were rejected under 35 USC 101 as being directed to non-statutory subject matter. The Examiner expressed the opinion that these are method or process claims that do not transform underlying subject matter, such as a particular article or materials, to a different state or thing, and referred to the Bilski case.

Applicant respectfully submits that Applicant's present claims are method or process claims that do actually transform underlying subject matter, and are entirely different to Bilski's claims.

In In re Bilski, the subject matter being claimed related to a concept for hedging cost risk of a commodity. Bilski's method claim initiates two sets of commodity transactions at two different fixed rates.

However, Applicant submits that the present invention being claimed is entirely different from the situation discussed in Bilski. Present claim 1 includes the steps of inserting a pH sensor into the tissue, directly measuring intracompartmental pH in the tissue with the pH sensor, and a

person then using the intracompartmental pH measurement to determine the presence or severity of ischemia and to diagnose a pathological condition.

The USPTO's brief in the Appeal to the Court of Appeals for the Federal Circuit, pages 8 to 9, summarized that in the Bilski case:

> The Board agreed with the Examiner that Bilski's claims were not patentable under 35 USC 101 for two reasons: (i) Bilski's claimed method failed to meet the requirement for a statutory "process" to transform matter or energy into a different state or thing, and (ii) it was a disembodied concept that represented nothing more than an abstract idea. A42-43; A50-51.

However, the present claims <u>do</u> transform matter or energy into a different state or thing and are <u>not</u> just a disembodied abstract concept, as will be explained below.

In reaching its decision, the Board found that Bilski's "claim did not require any computer or machine implementation and thus there was no implicit transformation of electrical signals. A47. Nor did the claim transform any physical matter into a different state or thing. Accordingly, the Board concluded that claim 1 did not qualify as a section 101 process." (USPTO's brief in the Appeal to the Court of Appeals for the Federal Circuit, page 9).

In contrast, Applicant's present claim 1 <u>does</u> require machine implementation by use of the pH sensor and there <u>is</u> an implicit transformation of signals by the pH sensor.

Furthermore, Applicant's present claim 1 <u>does</u> involve the transformation of physical matter into a different state or thing, as will now be discussed.

The Decision of the Board of Patent Appeals and Interferences, states that: "the Supreme Court has arguably defined a 'process' as 'an act, or series of acts, performed on the subject matter to be transformed and reduced to a different state or thing... The subject matter transformed may be tangible (matter) or intangible (some form of energy, such as the conversion of electrical signals

or the conversion of heat into other forms of energy (thermodynamics)), but it must be physical'" (page 17).

The Decision of the Board also confirms that "methods tied to a machine generally qualify as a 'process' under 35 USC 101 because machines inherently act on and transform physical subject matter" and that "Statutory processes are evidenced by physical transformation steps, such as chemical, electrical and mechanical steps" (page 18).

Note that the definition given there of what constitutes a physical transformation is extremely broad, encompassing chemical, electrical and mechanical steps.

The method of present claim 1 <u>is</u> tied to a machine (the pH sensor) and according to the above case law, therefore qualifies as a process under 35 USC 101 because the pH sensor inherently acts on and transforms physical subject matter, evidenced by physical transformation steps. Note again the contrast with the subject matter claimed in the Bilski case; a mere mental act with no bearing on the physical world.

Applicant's present claim 1 includes a first physical transformation step: the insertion of the pH sensor into the tissue. The physical act of insertion of the pH sensor necessarily transforms the tissue by being forced directly into the tissue, separating its fibres, for example, see at page 12, lines 19 to 26 of the application as filed, where it is disclosed that the pH monitor is placed in the muscle through the skin, and that the catheter is inserted through a cannula, placed generally parallel to the muscle fibres, into the muscle compartment adjacent to the fracture site. It is further disclosed, in the paragraph bridging pages 10 and 11 of the application as filed, that the catheter is inserted into skeletal muscle and connected to a pH recorder. This is unambiguously a physical act having physical effects in the real world.

Applicant's present claim 1 includes a second physical transformation step of directly measuring intracompartmental pH in the tissue with a pH sensor. This necessarily involves both physical and electrical transformation steps (the result of measuring the pH is an electrical signal) and

chemical and/or mechanical steps in order to measure the pH itself. The very act of obtaining the data relating to the pH measurement necessarily involves a physical transformative step.

On page 24, the Decision of the Board states that: "The court specifically held that transformation of data representing some real world quantity (a waveform in *Alappat*, an electrocardiograph signals from a patient's heartbeat in *Arrhythmia*, or discrete dollar amounts in *State Street*) by a machine was a practical application of a mathematical algorithm, formula or calculation that produced 'a useful, concrete and tangible result.'"

This is exactly the case with the present invention. The pH of a substance is known to be the cologarithm of the activity of dissolved hydrogen ions within that substance. A typical pH sensor on a pH meter is adapted to measure the activity and the concentration of H+ ions in its surroundings. In embodiments of the invention, the concentration and activity levels of H+ ions within the tissue interact in a chemical and/or physical manner with the contacts on the sensor end inserted within the tissue, and cause the sensor contacts to generate an internal signal within the pH sensor to indicate the activity and concentration of H+ ions in the area of tissue adjacent to the sensor contacts. Thus it is clearly apparent that the physical interaction of the H+ ions with the sensor contacts on the end of the probe that is inserted into the tissue necessarily results in some kind of signal transduction and transformation of energy between the chemical and physical concentration and activity of the H+ ions in the tissue outside the pH sensor and the electrical internal signal generated by the sensor contacts. The internal signal generated by the sensor contacts in the inserted end of the probe that corresponds to the external chemical concentration and activity values sensed by the pH sensor is then transmitted to a processor of a pH meter, and these data are then typically transformed again within the pH meter into electrical data corresponding to the cologarithm of the sensed concentration and activity values of the H+ ions in the tissue surrounding the sensor contacts embedded within the tissue. This electrical or electronic representation of the pH within the tissue is then typically transformed again within the processor of the pH meter into a physical representation in the form of the visible light

readout in an LED or LCD display or the like, typically on the pH meter, representing the real world quantitative value of the tissue pH, and accordingly is a practical, technical application that produces a useful, concrete and tangible result.

Also, page 27 of the Decision of the Board states: "Where the steps define a transformation of physical subject matter (tangible or intangible) to a different state or thing, as normally present in chemical, electrical and mechanical cases, there is <u>no question that the subject matter is statutory</u>".

Hence, the present case, as is normal in chemical, electrical and mechanical cases, defines a number of transformations of physical subject matter, and hence this invention also relates to statutory subject matter.

Also, it is of no consequence that some of the method steps in present claim 1 are performed by a human, because the Decision of the Board also confirms that "a statutory process involving a transformation or physical subject matter can be performed by a human" (page 18).

Turning now to the second reason for rejection of the Bilski claims (being merely an abstract idea), the Decision of the Board confirms that "'abstract ideas refer to disembodied plans, schemes, or theoretical methods" (page 20). The Board determined that Bilski's "claim 1 sought to patent an abstract idea, since it lacked any underlying subject matter being acted on" (USPTO's brief in the Appeal to the Court of Appeals for the Federal Circuit, page 10). Indeed, this is understandable because Bilski's business method for hedging cost risk of a commodity is a disembodied, theoretical method which has no technical application and no transformative effects on the physical world.

In contrast, in the present claims, the underlying subject matter being acted upon is the tissue, which is acted upon by the physical insertion of the pH sensor into the tissue. First, the physical act of insertion of the pH sensor necessarily transforms the tissue by being forced into the tissue, separating its fibres). Second, the step of using the pH sensor to measure the intracompartmental

pH is another example of the pH sensor acting on the tissue, because it necessarily has a physical interaction with the tissue (the chemical activity and concentration of hydrogen H+ ions in the tissue outside the sensor is transformed into an electrical signal within the sensor and then a visible e.g. LED or LCD reading corresponding to the chemical activity and concentration of H+ ions) in order to perform the act of measuring the pH.

Hence, unlike Bilski's claim which was merely to an abstract, disembodied and theoretical method, and which has no effect on the physical world, the present claims are <u>not</u> only directed to an abstract theoretical method and <u>do</u> have a transformative, physical effect on the surrounding physical environment.

The fundamental reason for the existence of the Bilski case is to draw a distinction between methods which are patentable and methods which are not because of being merely abstract ideas lacking in transformative effect in the real physical world. The USPTO's brief in the Appeal to the Court of Appeals for the Federal Circuit, page 4, describes that "since the Court's decisions in *State Street* and *AT & T*, many patent applicants appear to have assumed (as does Bilski) that the sole test for patent eligibility is whether the invention produces a useful, concrete and tangible result." This has led to the filing of "an unprecedented number of patent applications relating to subject matter that arguably does not fall within the traditional rubric of 'inventions' in the 'useful arts'". The Bilski case is now aiming to exclude method claims in patent applications that "attempt to cover business concepts themselves, without any requirement for processing one set of data into another."

However, the Applicant's present claim 1 is not a business concept, is more than a purely abstract concept, does include the processing of data, does include real-world physical apparatus, and does include a transformative effect in the real world. Hence, the Applicant's present claim 1 does indeed relate to statutory subject matter as defined by 35 USC 101.

<u>Rejection of claims 1-3, 5-9 and 11 under 35 USC 103(a)</u>

The Examiner acknowledged that Applicant's previous arguments were considered and were found to be persuasive.

However, claims 1-3, 5-9 and 11 are now rejected under 35 USC 103(a) as being unpatentable over Fiddian-Greene et al (US 6,238,339) in view of Sacristan (US 5,158,083).

As acknowledged by the Examiner, a first difference between claim 1 and Fiddian-Greene is that Fiddian-Greene fails to include the step of <u>directly</u> measuring intracompartmental pH in the tissue. Instead, column 2, lines 27 to 32 confirms that the measurement of pH is obtained indirectly, by measuring the partial pressure of carbon dioxide in the lumen of the gut and measuring the bicarbonate concentration in arterial blood and using these two values in the Henderson-Hasselbalch equation to calculate pH. Hence, the first difference is that Fiddian-Greene does not involve direct measurement of pH.

A second difference is that Fiddian-Greene fails to disclose the step of inserting a pH sensor into a tissue.

A third difference is that Fiddian-Green does not actually measure intracompartmental pH in the tissue at all, whether directly or indirectly.

The Examiner asserted that Fiddian-Greene does disclose inserting a pH sensor 42 into a tissue, e.g. an internal organ, and that Fiddian-Greene discloses indirectly measuring intracompartmental pH. However, neither of these assertions are correct.

The abstract of Fiddian-Greene discloses that the tonometric catheter is introduced into a hollow internal organ. Furthermore, column 3, lines 53 to 55 and column 6, lines 20 to 22 both also confirm the catheter is introduced at a desired site within the gut (or other hollow organ). Additionally, column 2, lines 27 to 32 confirms that what is being measured by the tonometric catheter is the partial pressure of carbon dioxide in the lumen of the gut. "Lumen" means the

inside space of a tubular structure, surrounded by epithelial tissue. So, Fiddian-Greene uses a tonometric catheter to measure the partial pressure of carbon dioxide in the inside space in the middle of the tubular gut, and at no point does the tonometric catheter pass through any epithelial layer, or any other tissue type. This is completely different from the claimed method of inserting a pH sensor into a tissue to measure the intracompartmental pH within a compartment of the tissue.

Further confirmation that the tonometric catheter is <u>not</u> inserted into a tissue is clearly shown in the drawings. Fig 4 shows a tonometric catheter including tubing 62. Figs 3 and 6 show the tonometric catheter in use in the stomach. Figs 7 and 8 show the tonometric catheter in use in the colon. As shown explicitly in all of Figs 3, 6, 7 and 8, in no case is the tonometric catheter actually inserted <u>into</u> a tissue. Instead, the tonometric catheter sits within the hollow inside of the hollow organ. Fig 3 shows particularly well that the tonometric catheter is not inserted into any tissue and is actually spaced from the stomach lining tissue.

It is important to note that "located within" does not mean the same as "inserted into." Fiddian-Greene's catheter is located within the stomach, which has a stomach wall made of epithelial tissue. However, Fiddian-Greene's catheter is not inserted into the epithelial tissue of the stomach wall. To all intents and purposes, Fiddian-Greene's catheter is anatomically external to the body because it has travelled through an orifice of the patient's body from the mouth to the stomach, but at no point has it actually penetrated the patient's body tissue.

Furthermore, as shown in Fig 4, the end of the tubing is smooth and rounded and is not remotely suitable for penetrating a tissue. In fact, since there is absolutely no intention or teaching in Fiddian-Greene to insert the tonometric catheter into a tissue, it is implicit that the tubing 62 is specifically designed not to damage or break the tissue wall.

Hence, Fiddian-Greene merely discloses locating a tonometric cathether in proximity to a tissue, within the hollow space inside a hollow internal organ. Fiddian-Greene does not disclose the claimed step of inserting a pH sensor into a tissue.

In respect of the third difference (measuring intracompartmental pH in the tissue), since the tonometric catheter is not actually inserted into a tissue compartment, it cannot, by definition, measure the pH within that tissue compartment. In anatomy, a tissue compartment is bounded by an outer layer (e.g., of fibrous connective tissue) and itself contains a tissue (e.g., muscle tissue) within that boundary. "Intracompartmental pH" means the pH level within a compartment surrounded by the boundary. Hence, it follows that a pH sensor would have to be inserted INTO the compartment so that it passes through the tissue forming the boundary of that compartment in order to measure the intracompartmental pH within that compartment.

In the case of the present invention, the pH sensor is indeed inserted into a compartment to measure the intracompartmental pH, for example, see at page 12, lines 19 to 26 of the application as filed, where it is disclosed that the pH monitor is placed in the muscle through the skin, and that the catheter is inserted through a cannula, placed generally parallel to the muscle fibres, into the muscle compartment adjacent to the fracture site.

In contrast, Fiddian-Greene's tonometric catheter is located in a hollow space, inside a hollow organ (see Fig 3), but NOT within a tissue and certainly not within a muscle compartment.

Hence, in summary, amended claim 1 is novel over Fiddian-Greene for at least the following reasons:

1. Fiddian-Greene does not disclose direct measurement of pH.

2. Fiddian-Greene fails to disclose the step of inserting a pH sensor into a tissue.

3. Fiddian-Green does not actually measure intracompartmental pH in the tissue at all, whether directly or indirectly.

For the Examiner's obviousness rejection to be upheld, all three of the above features would have to be suggested by Sacristan AND it would have to have been obvious to modify Fiddian-Greene in view of Sacristan to include all three of these features.

If the person of ordinary skill in the art were to consult Sacristan, he would actually find that none of these differentiating features are suggested by Sacristan, as will now be explained.

1. Sacristan does not disclose direct measurement of pH.

Referring to column 1, Sacristan's device relates to a pCO_2 (partial pressure of carbon dioxide) sensor for measuring carbon dioxide in the body (lines 7 to 11). A fall in the intramucosal pH can be calculated from a measurement of pCO_2 using the Henderson-Hasselbalch equation (lines 13 to 16). Commercially available pCO_2 sensors have been found to be inadequate (lines 30 to 32), and the Sacristan invention concerns overcoming the shortcomings of the prior art pCO_2 sensors (lines 40 to 44). Hence, from this we learn already that Sacristan, like Fiddian-Greene, is concerned with a measurement of pCO_2 used to indirectly calculate pH using the Henderson-Hasselbalch equation. Sacristan is therefore essentially concerned with an improvement of the equipment used in Fiddian-Greene's tonometric method, and does not provide the missing feature of the direct measurement of pH.

Although Sacristan calls the component referenced 14 a "pH probe", this is misleading, since the pH probe 14 is not actually being used to measure pH. The pH probe 14 is instead being used as a reference electrode for the pCO_2 probe 10 and there is not a single disclosure in Sacristan of anything that takes a direct measurement of pH. In contrast, what is actually being measured is the quantity of CO_2 in the reference chamber 20 compared with the quantity of CO_2 in the test chamber 18. Hence, like Fiddian-Greene, Sacristan does not disclose direct measurement of pH.

2. Sacristan fails to disclose the step of inserting a pH sensor into a tissue.

Considering now difference 2 (the step of inserting a pH sensor into a tissue), perhaps unsurprisingly, as both Fiddian-Green and Sacristan disclose tonometry methods for measuring pCO_2, Sacristan's pCO_2 probe 10 is also "positioned in the hollow organ (in this case the stomach) where measurement is desired" (column 5, lines 17 to 20). Fig 2 clearly shows the tonometric catheter sitting within the inside hollow of the stomach spaced from the wall of the

stomach and not inserted within the patient's body tissue. Looking at Fig 1, it is actually impossible for the pH sensor 14 to be inserted into the patient's body tissue because the end cap 48 and the Nylon mesh spacer 46 seal the pH sensor 14 within the test chamber 18 and specifically prevent the pH probe 14 from penetrating into the tissue of the patient, which would be an undesirable modification of Sacristan.

Hence, like Fiddian-Greene, Sacristan also fails to disclose the step of inserting a pH sensor into a tissue.

3. Sacristan does not actually measure intracompartmental pH in the tissue at all, whether directly or indirectly.

Considering now difference 3, (measurement of intracompartmental pH), this feature is also lacking in Sacristan for the same reasons that it is lacking from Fiddian-Greene.

Since the tonometric catheter is not actually inserted into a tissue, it cannot, by definition, measure the pH within that tissue. A pH sensor must be inserted INTO a compartment in order to measure the pH within that compartment. In contrast, Sacristan's tonometric catheter is located in a hollow space, inside of the hollow stomach (see Fig 2), but it is NOT within a tissue and certainly not within a muscle compartment. Hence, it is not possible for Sacristan's tonometric catheter to measure intracompartmental pH, whether directly or indirectly. Hence this would reinforce to a skilled person consulting the combined disclosures of Fiddian-Greene and Sacristan that it is best to use a non-invasive probe that does not penetrate the tissue of the body.

Thus, Sacristan does not suggest any of the features of the present claim 1 that are missing from Fiddian-Greene. In particular:

1. Neither Fiddian-Greene nor Sacristan discloses direct measurement of pH. Instead, both directly measure pCO_2 and use this result in the Henderson-Hasselbalch equation to calculate pH.

2. Neither Fiddian-Greene nor Sacristan discloses the step of inserting a pH sensor into a tissue. Instead, both use a pCO_2 sensor mounted on a tonometric cathether that is inserted through an orifice in the body into a hollow space within a hollow organ of the body. In both cases, the sensor is located some distance away from the actual walls of the organ, and in neither case is the sensor inserted into the patient's body tissue.

3. Neither Fiddian-Greene nor Sacristan discloses measuring intracompartmental pH in the tissue at all, whether directly or indirectly. Since the sensors in both cases are not inserted into a compartment of the body, it follows that these sensors physically cannot measure the <u>intra</u>compartmental pH within that compartment.

Thus, as neither Fiddian-Greene nor Sacristan discloses any of these three features of amended claim 1, it follows that even reading Fiddian-Greene in the light of Sacristan cannot possibly lead the person of ordinary skill in the art to the present invention. Instead, the person of ordinary skill in the art would be reassured in his view that calculating pH using a measurement of pCO_2 obtained using a tonometry method is the best way forward, since both documents teach this.

Hence, amended claim 1 is non-obvious over Fiddian-Greene, in view of Sacristan.

<u>Claims 2, 3, 5 to 9 and 11</u>

Claims 2, 3, 5 to 9 and 11 are all dependent on claim 1, and thus are also novel and non-obvious, at least by virtue of this dependency.

Request for Allowance

It is thus believed that the application is now allowable and notification to this effect is earnestly solicited. Should the Examiner have any questions or comments regarding Applicants' amendments or response, he is asked to contact Applicants' undersigned representative at (215) 988.3309. Please direct all correspondence to the below-listed address. If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573.

Respectfully submitted,

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